



Continuing Review Form

I. STUDY INFORMATION	
Principal Investigator:	
Protocol Number:	
Sponsor name and/or Funding Agency:	

II. SUBJECT INFORMATION											
<p>1. Have any subjects been screened at your site since initial IRB approval? <input type="checkbox"/> Yes <input type="checkbox"/> No*</p> <p>* If No, skip to section IV of this form</p>											
<p>2. Is your site currently recruiting for this study? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>											
<p>3. Number of subjects who signed an informed consent form:</p>											
<p>4. Number of screen failures:</p>											
<p>5. Number of subjects who entered into the study (i.e. randomized for randomized trials):</p>											
<p>6. Of the patients who entered the study, indicate the totals below:</p> <table border="1"> <tr> <td>Currently Active in Study:</td> <td>Lost to Follow Up:</td> </tr> <tr> <td>Completed:</td> <td>Withdrew due to AE:</td> </tr> <tr> <td>Withdrew Consent:</td> <td>Other*:</td> </tr> <tr> <td>Discontinued by Sponsor:</td> <td></td> </tr> <tr> <td colspan="2"> <p>* Indicate reasons for subject withdrawal or early termination for all subjects included in "other" category above:</p> </td> </tr> </table>		Currently Active in Study:	Lost to Follow Up:	Completed:	Withdrew due to AE:	Withdrew Consent:	Other*:	Discontinued by Sponsor:		<p>* Indicate reasons for subject withdrawal or early termination for all subjects included in "other" category above:</p>	
Currently Active in Study:	Lost to Follow Up:										
Completed:	Withdrew due to AE:										
Withdrew Consent:	Other*:										
Discontinued by Sponsor:											
<p>* Indicate reasons for subject withdrawal or early termination for all subjects included in "other" category above:</p>											
<p>7. Have any advertising materials been used for this study? <input type="checkbox"/> Yes <input type="checkbox"/> No</p>											

II. SUBJECT INFORMATION

8. If yes to item 7 above, were the advertising materials approved by Total IRB prior to use?

Yes No*

* If No, attach a copy of the materials and letter of explanation.

9. How many Serious Adverse Events (SAEs) have occurred at your site?

10. How many Adverse Device Effects (ADEs) have occurred at your site?

11. How many unanticipated problems have occurred at your site?

12. Have any vulnerable populations been enrolled at your site in this study? Yes* No

Indicate Vulnerable Populations enrolled:

- children
- prisoners
- pregnant women
- mentally disabled persons
- economically or educationally disadvantaged persons
- Other (specify):

*If Yes, was this population previously approved for enrollment by Total IRB? Yes No

III. SUBJECT DIVERSITY

Gender:

Percent (%) of subjects that signed informed consent form (ICF) that were male : _____ %

Percent (%) of subjects that signed ICF that were female : _____ %

Note: should total to 100%

Ethnicity:

Percent (%) of subjects that signed ICF that were Hispanic or Latino: _____ %

Percent (%) of subjects that signed ICF that were Not Hispanic or Latino: _____ %

Note: should total to 100%

Race:

Percent (%) of subjects that signed ICF that were African-American: _____ %

Percent (%) of subjects that signed ICF that were American Indian: _____ %

Percent (%) of subjects that signed ICF form that were Asian: _____ %

Percent (%) of subjects that signed ICF that were Caucasian: _____ %

Percent (%) of subjects that signed ICF that were Other Race: _____ %

Note: should total to 100%

IV. SAFETY

For this section answer the questions based on information since either your initial IRB approval or your last continuing review report (whichever is most recent):

<p>1. Have any participants at your site requested compensation for an injury associated with the study that has not already been reported to Total IRB? * If Yes, attach a letter of explanation.</p>	<p><input type="checkbox"/> Yes* <input type="checkbox"/> No</p>
<p>2. Is there any new information that could influence Total IRB's assessment of risk or benefit to subjects? * If Yes, attach a letter of explanation.</p>	<p><input type="checkbox"/> Yes* <input type="checkbox"/> No</p>
<p>3. Have there been any unanticipated problems, significant protocol deviations, or Serious Adverse Events (SAEs)/Adverse Device Effects (ADEs) that have not previously been reported to Total IRB? * If Yes, attach a letter of explanation regarding the delay as well as the appropriate reporting form.</p>	<p><input type="checkbox"/> Yes* <input type="checkbox"/> No</p>
<p>4. Was the informed consent presented to all subjects in an appropriate manner? * If No, attach a letter of explanation.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No*</p>
<p>5. Is the PI personally conducting and/or supervising this study? * If No, attach a letter of explanation.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No*</p>

V. SITE INFORMATION

For this section answer the questions based on information since either your initial IRB approval or your last continuing review report (whichever is most recent). If any item is answered YES, and the information has not been previously submitted and approved by Total IRB, submit information with this form including explanation for delay in reporting.

	Yes	No	Submitted and Approved by IRB?
1. Has your site experienced any problems protecting subject confidentiality?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Has your site been audited by the FDA, OHRP, Sponsor/CRO, or other regulatory agencies since your last review/approval?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Has your site received a Form FDA 483, Warning Letter, or other regulatory action since your last review/approval?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Have there been any professional sanctions, restrictions, disciplinary or legal actions involving study staff and/or your site(s) since your last review/approval?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Has there been a change in investigator, sub-investigator or immediate family member conflict of interest?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Has there been a change to local or state laws regarding research on human subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Has there been a negative change to community attitudes regarding research on human subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

V. SITE INFORMATION			
	Yes	No	Submitted and Approved by IRB?
8. Does your site currently require a change to any of the IRB-approved documents (e.g. Informed Consent Form, protocol, advertisements, change of address, etc.)? <i>If Yes, attach required changes and include appropriate Total IRB submission forms as applicable.</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

VI. PERSON COMPLETING FORM	
<p>I certify that the information contained in this form is complete and accurate and that no facts have been suppressed or misstated. I am requesting for Total IRB to review the information submitted and provide approval or disapproval information. I understand that Total IRB has the authority to oversee this study and suspend the research study at this site if necessary to protect the rights and welfare of the study subjects. I agree to provide all information requested to conduct initial and continuing reviews of this study on time. I understand that if information is not provided, Total IRB may suspend the study. I agree to conduct the study in accordance with the conditions above. The Principal Investigator (PI) is aware of all information in this form and I am authorized to submit to the IRB on the PI's behalf.</p>	
Form Completed By	Date
Title, Company	
Phone:	Email: